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PATENT  
(116142-00170)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Pilon et al.  
Serial No. : 09/898,616  
Filed : July 2, 2001  
For : ***METHODS FOR THE PRODUCTION OF PURIFIED  
RECOMBINANT HUMAN UTEROGLOBIN FOR THE TREATMENT  
OF INFLAMMATORY AND FIBROTIC CONDITIONS***  
Examiner : Rachel B. Kapust  
Group Art Unit : 1647

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P.O. Box 1450  
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Henry J. Cittone  
Name of Applicant, Assignee or Registered  
Representative

H. J. Cittone  
Signature

October 15, 2003  
Date of Signature

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**RESPONSE TO SEPTEMBER 15, 2003 RESTRICTION REQUIREMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Response is submitted in response to the Restriction Requirement issued on  
September 15, 2003 in connection with the above-identified application. The deadline for

response to the September 15, 2003 Restriction requirement is October 15, 2003. Accordingly, this Response is being timely submitted.

In response to the Official Action mailed September 15, 2003, Applicants hereby elect, with traverse, for further prosecution in this application that invention identified in the Official Action as Group II, Claims 35-55 and 74-78. This restriction requirement is respectfully traversed.

In the September 15, 2003 Restriction Requirement, the Examiner stated that restriction to one of the following inventions is required under 35 U.S.C. § 121:

- |           |   |
|-----------|---|
| Group I   | Claims 1-34, drawn to a bacterial expression system for production of recombinant human uteroglobin (rhUG), classified in class 435, subclass 69.1, 71.2, 243 or 260. |
| Group II  | Claims 35-55 and 74-78, drawn to a method of purifying rhUG and determining the purity of rhUG, classified in class 530, subclass 412.                                |
| Group III | Claims 56-72, drawn to an assay for determining the potency of rhUG, classified in class 435, subclass 7.1 or 7.8   |
| Group IV  | Claim 73, drawn to a method for measuring <i>in vitro</i> the binding of rhUG to fibronectin, classified in class 435, subclass 7.8.                                  |
| Group V   | Claims 79-100, drawn to a pharmaceutical composition comprising rhUG, classified in class 514, subclass 2.  |

It is respectfully requested that the restriction requirement be favorably reconsidered and withdrawn. Applicants maintain that a search of the prior art when examining claims 35-55 and 74-78 should reveal any prior art for the remaining claims, i.e., 1-34, 56-73 and 79-100.

Applicants note that MPEP § 803 states that if the search of an entire application can be made without serious burden, then the Examiner must examine it on the merits, even if it, as Examiner contends, includes claims to independent or distinct inventions.

Applicants submit that even if Groups I-V represent distinct inventions, a search of the subject matter of each group would not be a serious burden on the Examiner. Applicants note that MPEP § 808.02 states that even if related inventions are shown to be distinct, the Examiner must also show serious burden "by appropriate explanation."

Moreover, as a result of the GATT legislation limiting the term of a patent to twenty years from its effective filing date, the delay in the examination of the non-elected claims will likely result in the patent term for these claims being unnecessarily shortened.

Furthermore, it is likely that the same Examiner would be in charge of the divisional application; but since that divisional application will be examined at a much later date, the Examiner will have to conduct a duplicate, redundant search at the time she examines the divisional application. Alternatively, if a different Examiner is assigned to the divisional application, a significant loss of PTO efficiency would be incurred as a result of the examination of that divisional case.

In view of the foregoing, withdrawal of the requirement for restriction is respectfully requested.

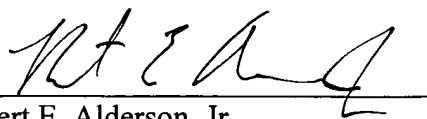
If a telephone interview would be of assistance in the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at her convenience at the number provided below.

No fee is believed to be necessary in connection with the filing of this Amendment. However, if any additional fee is required, the Commissioner is hereby authorized to charge such fee(s) to Deposit Account No. 50-0540.

Early and favorable examination on the merits is respectfully requested.

Respectfully submitted,

Dated: October 15, 2003

By: 

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